

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



RESEARCH CENTRE "BIOFORM"

NEWS
ABOUT THE COMPANY
THE PARTNERS
PLASTIC SURGERY
OSTEOARTHRITIS
URINARY INCONTINENCE
OUR PRODUCTS
F.A.Q.
FOR THE EXPERTS
CONTACTS

Plastic surgery

Bloodless and minimal invasive methods of correction of appearance become very popular at people who want to look young and attractive. But in a pursuit of beauty it is important to not make the wrong choice of correcting preparation.

To preparations for correction of appearance, long time taking place in a body of the person, increased requirements of safety are demanded. It is very important, that the alien substance of a preparation was not torn away by an organism, did not provoke allergic reactions, had no toxic and cancerogenic properties. But it is frequent on the market appear insufficiently investigated preparations which are even not having the certificate and the sanction of Ministry of Health. Application of such preparations, certainly, more accessible from the point of view of the price in comparison with safe analogues, can have the most sad consequences both in short-term, and in long-term prospect.

Gels for correction of appearance.

To gels for correction of appearance rather rigid requirements are demanded. First, they should not cause an allergy, inflammations and not to have cancerogenic or toxic action on an organism; second, they should not migrate from a place of input in environmental tissues; also the technology of their manufacture should give an opportunity for sterile packing and storage. The adjusting gels, adequate to these requirements, tried to synthesize from polymers as natural so an artificial origin. For a basis of natural gels were taken polymers that the skin of the person consists: hyaluronan acid and collagen. It was meant, that "native" substances of a human body would not cause allergic reaction. But it was obvious that such preparations are short-lived because they are resolving.

Such gels on a basis hyaluronan acid are applied to elimination of wrinkles of different depth, also corrections of lips, cheeks and a chin. They, as a rule, support cosmetic effect about 8-12 months.

Collagen gels are so short-lived. To prolong cosmetic effect, at some materials together with collagen are present as well micro spheres of methilcrolylat which size is comparable with the sizes of cells, that interferes with migration of a preparation. After resolving the injected collagen, micro sphere become a basis for formation of collagen capsules. One of the most serious problems connected to injection of gels on the basis of collagen is some probability of development allergic reaction to collagen at patients. In this case, besides the centers of an inflammation in a place of input of a preparation, also can arise the intolerance to meat food, as is known containing collagen.

Polyacrylamid gels

The history of application polyacrylamid gels (PAAG) in medicine totals some decades. In 60th

years PAAG was tried as a material for rigid contact lenses, but it has not received a wide circulation. And at the end of 70, in Soviet time, development of the materials, capable to comprise a medicine have begun, and PAAG has drawn attention of developers. That is polyacrylamid gel was initially applied to gradual input of a medicine in an organism, and only then have found out such interesting fact, that the human body almost does not react to it in any way. The usual capsule is formed of a connecting tissues, but is much more thin, than in a case, for example, with silicon implants. In 1982-83 for the first time PAAG have started to try in plastic surgery. But because of lacks of the "know-how" and a technique of introduction were marked numerous cases of complications. And only to 1992-93 the Russian scientist Lopatin V.V. found the optimum structure of polyacrilamid gel. Actually, then birth of preparation "Formacryl" was held. In 1995 after serious and scrupulous researches, "Formacryl" has received the sanction of Ministry of Health. Then within three years of research of short-term and long-term influence of "Formacryl" proceeded independent experts in Italy - on laboratory animals and volunteers. It was determined, that, at least, in small volumes (up to 5 ml) it is absolutely safe. And for correction of lips, elimination of wrinkles and other defects on the person is an ideal material. Only after such, positive conclusion of the Italian researchers, this preparation started to be applied in Italy and Russia. For today our company develops the advanced material for correction of wrinkles and fillings of deficit of soft tissues "Argiform". The given product is deprived all lacks of materials of the previous generation and moreover has antibacterial action that distinguish it from all weight of gels for correction of wrinkles.

[News](#) | [About the company](#) | [The partners](#) | [Plastic surgery](#) | [Osteoarthritis](#)
[Urinary incontinence](#) | [Our products](#) | [F.A.Q.](#) | [For the experts](#) | [Contacts](#)



NEWS
ABOUT THE COMPANY
THE PARTNERS
PLASTIC SURGERY
OSTEOARTHRITIS
URINARY INCONTINENCE
OUR PRODUCTS
F.A.Q.
FOR THE EXPERTS
CONTACTS

RESEARCH CENTRE "BIOFORM"

Our products



WHAT IS Argiform?

Argiform is an absolutely innovative implant in the sector of cosmetic surgery. For the first time, in fact, medical science employs a product comprising 95% apyrogenous water and 5% of a polyacrylamide, a synthetic polymer that has already been used in cosmetics. This association guarantees maximum softness of touch; the implant (which can be injected) retains more or less the same consistency as tissue, without causing unattractive artificial effects, either visible or palpable.

WHERE IS Argiform USED?

Argiform is used in medicine and plastic surgery to correct any type of secondary imperfection due to deficiency of substance: from fine wrinkles to prominent nasolabial folds; acne scars, post-operative scars, secondary scars caused by burns, and post-traumatic scars. Argiform is also the ideal choice of implant for contouring the lips, cheekbones, etc. Unlike other fillers, Argiform (thanks to its absolute degree of bio-compatibility) can also be used for large substance deficits without the risk of causing unexpected side effects.

IS Argiform SAFE?

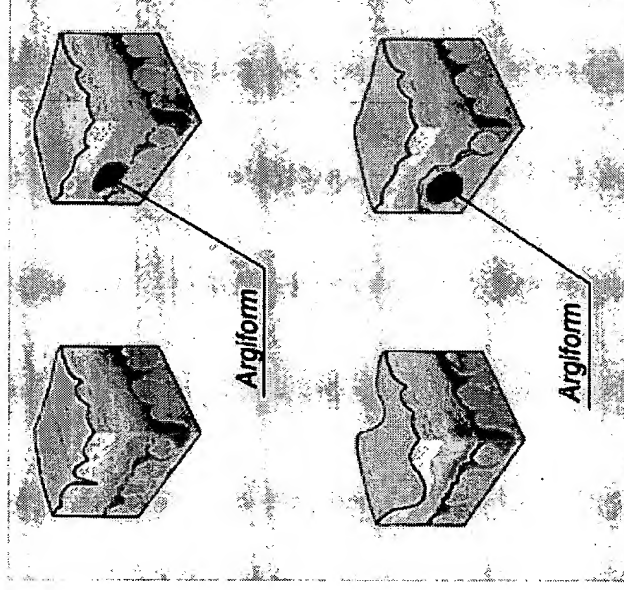
Six years of rigorous and scrupulous clinical experimentation have enabled Argiform to provide the maximum safety. The very special, cutting-edge production technique - an exclusive patented process, employed for this product - guarantees (unlike numerous other similar products) the absence of the toxic monomer that usually characterises these polymers - and which is responsible for all the well known devastating secondary effects. Analyses demonstrate that Argiform™ is: non toxic, antibacterial, non-sensitising, non-mutagenic, biocompatible, permanent, removable, and physically and chemically stable. An added advantage of Argiform is that it is absolutely radio transparent, thus allowing differential diagnosis with structures at the implant site, if necessary.

CAN ANYONE USE Argiform?

From studies conducted so far, it has been shown that Argiform is an absolutely safe product; in fact, no sensitisation test is necessary since it has never caused any type of allergic reaction. In any event, it is advisable to inform the doctor regarding predisposition to allergies (polyallergic subjects).

WHAT HAPPENS AFTER THE IMPLANT?

Immediately after the introduction of Argiform a thin natural physiological capsule is formed (forming the actual endoprosthesis), which encloses the substance, thus facilitating identification and removal (easy, not traumatic), if necessary, at any moment. The oedema that develops immediately following the implant (in normal conditions) is minimal and does not last more than 20 minutes. There is also slight redness in the area following the injection, but this disappears within a few minutes. Cosmetics can be used after the implant without any risk of interaction. Within a few days, any bruising or swelling that may have existed in the area disappears (no palpable changes as it consists of 95% of water); on the other hand, there is a pleasant aesthetic effect.



HOW LONG DOES Argiform LAST ONCE INJECTED?

Argiform belongs to the category IIb of "medical devices" and therefore substances that cannot be reabsorbed; in fact it can be left infinitely (unless it is specially removed) like any other artificial prosthesis. The aesthetic effect caused by Argiform is, of course, not eternal since, with the passage of time, the skin ages and the tissues (mainly the muscles) change position and shape, creating new wrinkles and imperfections "mechanically" supported, however, by the substance

injected.

IS THE IMPLANT PAINFUL?

Like any other injection, Argiform also causes pain, which only lasts as long as the injection. In any event, any type of anesthesia can be used (even local) to relieve the pain, according to the doctor's discretion.

CAN THE IMPLANT BE DONE AT ANYTIME OF YEAR?

Certainly. Heat does not interfere with the substance unless the temperature is very high. Remember that Argiform™ is steam sterilized at a temperature exceeding 120°C. It is advisable, however, to avoid exposure to UVA and UVB rays for at least 24 hours after the implant; this is to prevent any change in the secondary pigmentation during the temporary inflammation caused by the implant.



WHAT IS DAM+?

DAM+ is the newest implant used in urology for elimination of stress urine incontinence. Since 1980 the Russian medicine studied the substance consisting of 95 % apyrogenous water and 5 % on a polyacrylamide basis, having unique functions. It was a unique synthetic material that practically on 100 % was biocompatible with human organism. Only one lack was its instability to growth of bacteria and an opportunity of development of an inflammation in a human organism. At last in 1995 the Russian scientists invented the absolute new substance that had united all positive qualities of the previous material and in the same time has antibacterial properties, due to addition in it ions of silver. At introduction this implant in a human organism the consistence becomes similar to soft tissue that allows using it for maintenance of muscles of a urethra in the necessary position.

IS DAM+ SAFE?

The largest Russian institutes checked implant DAM+™ during 6 years. All works were directed on studying of safety of a material. Uniqueness of the "know-how" of DAM+™ has allowed it to confirm absolute safety, and the implant was approved by Ministry of Health of the Russian Federation. Researches show, that DAM+: nontoxic, non-sensitizing, non-mutagenic, non-allergic, biocompatible, constant, physically and chemically steady preparation having constant antibacterial action.

WHERE DAM+ CAN BE USED?

DAM+ is used in urology for elimination of stress urine incontinence. The "stress" in stress urinary incontinence is not associated with mental or emotional stress, but rather with increases in physical stress or pressures exerted on the body. Simple everyday activities such as laughing, sneezing, or coughing can exert enough pressure on the bladder to trigger accidental urine leakage for millions. Leakage also can occur with more strenuous stress such as lifting heavy objects, dancing, jogging, or during aerobics. Injection of DAM+ helps the weak muscles of the bladder neck by adding bulk to the area. The added bulk allows the bladder neck to close enough to help stop urine from leaking. When the woman decides to empty her bladder, the opening from the bladder into the urethra expands, allowing urine to pass through.

WHAT IS A PROCEDURE OF INJECTION DAM+?

After the area is numbed, a rigid, hollow tube called a cystoscope is inserted into the urethra, allowing the physician to visualize the open bladder neck. A thin needle is inserted through the cystoscope and DAM+ is pushed through the needle into the numbed areas. The needle and cystoscope are then removed and the treatment is complete. The procedure can be accomplished in less than 30 minutes. At once after the treatment patient can test the effect.

WHO CAN USE DAM+?

It is possible to use DAM+ at any form of stress urine incontinence

WHAT OCCURS AFTER INTRODUCTION?

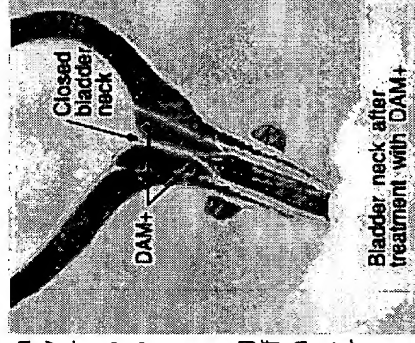
Directly after introduction DAM+ forms "pillow" in a urethra and provides necessary locking functions that completely allows to get rid from stress urine incontinence. A bit later around of a implant the thin natural physiological capsule, which fences off substance from tissues, is formed, thus, facilitating its identification in a urethra.

HOW LONG THE EFFECT FROM USING DAM+ LASTS?

Material DAM+ does not resolve and does not collapse during all human life that allows to receive effect for a long time. If disease renewal in case of proceeding easing sphincter, in that case recurrence of procedure is required in 7-10 years. For today it was not observed any case of destruction or resolving a implant in a human organism.

IS PROCEDURE OF INJECTION DAM+ PAINFUL?

Procedure will be carried out under local anesthesia and it is practically painless.





WHAT IS NOLTREX?

NOLTREX is the newest implant used in orthopedy and traumatology for treatment osteoarthritis. Since 1980 the Russian medicine studied the substance consisting of 95 % apyrogenous water and 5 % on a polyacrylamide basis, having unique functions. It was a unique synthetic material that practically on 100 % was biocompatible with human organism. Only one lack was its instability to growth of bacteria and an opportunity of development of an inflammation in a human organism. At last in 1995 the Russian scientists invented the absolute new substance that had united all positive qualities of the previous material and in the same time has antibacterial properties, due to addition in it ions of silver. At introduction this material in a human organism the consistence becomes similar to synovium liquid in joints that allows using it for treatment osteoarthritis.

IS NOLTREX SAFE?

The largest Russian institutes checked implant NOLTREX during 6 years. All works were directed on studying of safety of a material. Uniqueness of the "know-how" of NOLTREX has allowed it to confirm absolute safety, and the implant was approved by Ministry of Health of the Russian Federation. Researches show, that NOLTREX: nontoxic, non-sensitizing, non-mutagenic, non-allergic, biocompatible, constant, physically and chemically steady preparation having constant antibacterial action.

WHERE NOLTREX CAN BE USED?

NOLTREX is used in orthopedy for replacement synovium liquid. In healthy joint, synovial liquid lubricates the joint and is needed for the joint to function properly. Joint fluid is made up mostly of a substance called hyaluronan. In osteoarthritis, joints do not have enough greasing and cartilage structure begins to change. Deficit of synovium liquid cause a mechanical contact of bones, without enough of greasing that conducts to destruction of the joint, and to the subsequent destruction of bones. Material NOLTREX is entered in a joint and provides sufficient greasing that allow to stop a destruction of a joint and a pain. Due to the biocompatible qualities the material does not render any influence on a human organism and once injected allows to forget about pain in a joint.

WHAT IS A PROCEDURE OF INJECTION NOLTREX?

The necessary quantity of a preparation is entered in an articulate cavity with the help of a thin needle under local anesthesia... The procedure can be accomplished in less than 30 minutes and does not demand the subsequent presence in a hospital. At once after the treatment patient can test the effect.

WHO CAN USE NOLTREX?

It is possible to use NOLTREX at 1,2,3 stage of osteoarthritis.

WHAT OCCURS AFTER INTRODUCTION?

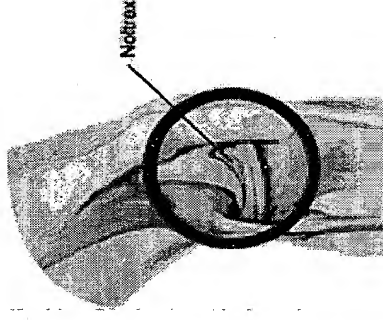
Directly after introduction NOLTREX forms "pillow" in a joint and provides good greasing effect due to that patient painful sensations is stopped. A bit later around of a material the thin natural physiological capsule, which fences off substance from tissues, is formed, thus, facilitating its identification in a joint.

HOW LONG THE EFFECT FROM USING NOLTREX LASTS?

Implant NOLTREX does not resolve and does not collapse during all human life that allows to receive effect for a long time. On assurance of the manufacturer the effect from application is kept on all life, on already confirmed data of researches a minimum for 6 years. For today it was not observed any case of destruction or resolving a material in a human organism.

IS PROCEDURE OF INJECTION NOLTREX PAINFUL?

Procedure will be carried out under local anesthesia and it is practically painless.



[|News|](#) [|About the company|](#) [|The partners|](#) [|Plastic surgery|](#) [|Osteoarthritis|](#)
[|Urinary incontinence|](#) [|Our products|](#) [|F.A.Q.|](#) [|For the experts|](#) [|Contacts|](#)